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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,588	09/15/2003	Sven Schreder	MERCK-2168D1	8058

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

NOTIFICATION DATE	DELIVERY MODE
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12/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No. 10/661,588	Applicant(s) SCHREDER ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A previous indication of finality is withdrawn.

A new title and an amended Abstract are noted.

Applicants' arguments with respect to claims 1, 3-5 and 9-16 that were rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al., U.S. Patent 3,808,332, in view of Lindenbaum E., WO 93/04691, and further in view of Jacobs et al., US 2005/0003491, in the last Office Action, have been considered but are moot in view of the new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al., U.S. Patent 3,808,332, in view of Jacobs et al., US 2005/0003491.

Reynolds teaches a combination of L-thyroxine and L-triiodothyronine that are physically admixed. Therefore, no organic solvent is present. See column 7, lines 65-67. See Composition I, column 7, where cornstarch is employed as a filler, and Composition J, where lactose and microcrystalline cellulose are employed as fillers. As required by instant claim 3, Reynolds teaches a concentration range of l-thyroxine of 100-300 mcg. Fillers such as lactose, maize starch and microcrystalline cellulose are conventional excipients. A micronized form of levothyroxine with a particle size

between 5 and 25 μm is conventional. Reynolds fails to include gelatin in the combination.

However, Jacobs teaches the inclusion of gelatin in solid pharmaceutical formulations such as tablets. See page 174, paragraph 4072. Gelatin is conventionally employed as a binder in tablet formulations because of its well-established cohesive qualities. One skilled in the art of formulation chemistry would have been motivated to prepare pharmaceutical formulations comprising L-thyroxine and, optionally, triiodothyronine, utilizing gelatin as a binder, in a solid form without organic solvents.

The showing presented in the Declaration filed February 13, 2008 under 37 CFR 1.132, is not commensurate in scope with the present claims. While Formulations B and C were demonstrated to have increased stability of levothyroxine, said formulations are drawn to specific ratios and amounts of active agent and excipients, whereas the instant claims are in no way limited to any particular amounts of active compound and gelatin. Further, in Formulation A, it is unclear whether or not hydroxypropyl methylcellulose (HPMC) imparts an unexpected *destabilizing* effect on levothyroxine sodium. If such were the case, it would not be gelatin providing an unexpected stabilizing effect, but rather HPMC providing an unexpected destabilizing effect. As such, in the absence of a showing that the alleged stabilizing effect of gelatin occurs over a broad range of amounts and ratios of active agent and gelatin in the claimed tablets, the Examiner is not persuaded that Applicants have demonstrated an unexpected result commensurate in scope with the claims. Furthermore, Applicants have only provided a comparison of HPMC and gelatin as binders. It cannot therefore

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be said that gelatin provides an unexpected stabilizing effect without showing comparisons to other known pharmaceutical binders.

No claim is allowed. However, favorable consideration would be given to claims drawn to the formulations disclosed in Examples 1-3 on pages 5-7 of the specification.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 15, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614